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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,140	11/21/2000	Brian Hawtin	2000-0702.OR	6011
7590	07/28/2004		EXAMINER WELLS, LAUREN Q	
Mark J Burns 1130 TCF Tower 121 South Eighth Street Minneapolis, MN 55402			ART UNIT 1617	PAPER NUMBER

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/701,140

**Applicant(s)**

HAWTIN, BRIAN

**Examiner**

Lauren Q Wells

**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3,5,9,11-13,17,28,32 and 33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13 is/are allowed.
- 6) ☒ Claim(s) 3,5,9,11,12,17,28,32 and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 3, 5, 9, 11-13, 17, 28, 32-33 are pending. The Amendment filed 6/24/04, cancelled claims 1, 4, 15, 21-23, amended claims 3, 5, 9, 11-12, 17, 28, and added claims 32-33.

The cancellation of claim 1 in the amendment filed 6/24/04 is sufficient to overcome the 35 USC 112 rejection in the previous Office Action.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 5, 11, 17, 28, and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Totten et al. (GB 2202145) in view of Jacobs et al. (5,939,085) and Sang et al. (6,143,310).

The instant invention is directed toward a method for treating a skin condition of a human patient comprising providing a composition comprising an amphoteric surfactant, a polypropoxylated cetyl alcohol, a polar selected from sodium cromoglycate and nedocromil sodium, and an aqueous and oil phase, and applying the composition to the skin.

Totten et al. teach compositions of nedocromil for dermatological use. Oil-in-water emulsions are preferred forms of the compositions. The oil phase can comprise surfactants, such as cetomacrogol ethers, wherein cetomacrogol ether is an ethoxylated cetyl alcohol. Topical administration of the composition is disclosed. For the skin conditions recited in instant claim 17, see page 7, lines 12-23. The composition is filled into 20ml tubes. The reference lacks

Art Unit: 1617

polypropoxylated cetyl alcohol and an amphoteric surfactant. See pg. 2, line 18-pg. 3, line 7; pg. 4, line 1-pg. 5, line 5; pg. 6, lines 19-22; pg. 7, lines 5-23; pg. 9-pg. 12.

Jacobs et al. teach skin smoothing compositions. Oil-in-water emulsions are taught, wherein disodium cocoamphodiacetate is a preferred surfactant. Disodium cocoamphodiacetate functions as an oil-in-water emulsion stabilizer and as a skin smoothing agent. See Col. 4.

Sang et al. teach cosmetic compositions. PPG-5-Ceteth is taught as a preferred alkoxyated cetyl alcohol that acts as a surfactant and solubilizes negatively charged active agents. See Col. 10.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the disodium cocoamphodiacetate of Jacobs et al. to the oil-in-water emulsions of Totten et al. because of the expectation of stabilizing the oil-in-water emulsions and smoothing the skin.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the PPG-5-ceteth of Sang in substitution for the cetomacrogol ether of Totten et al. because a) Sang et al. and Totten et al. are both directed toward skin cosmetic compositions; b) Totten et al. teach that additional surfactants can be added to his composition, especially alkoxyated surfactants; c) Sang et al. teach PPG-5-ceteth as both polyethoxylated and polypropoxylated, wherein these compounds are useful as surfactants for stabilizing emulsions and negatively charged active agents; thus, one of skill in the art would be motivated to substitute one for the other because of the expectation of achieving similar surfactant properties and as providing stability to the negatively charged active agent.

Art Unit: 1617

The claims are directed to a composition comprising an amphoteric surfactant, a polypropoxylated cetyl alcohol, and sodium cromoglycate or nedocromil sodium. Any properties exhibited by or benefits provided the composition are inherent and are not given patentable weight over the prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not inherently possess the same properties as instantly claimed product. The combined prior art teaches compositions containing the same components as instantly claimed, which would inherently provide transdermal transmission of the polar drug as instantly claimed. Applicant has not provided any evidence of record to show that the prior art compositions do not exhibit the same properties as instantly claimed.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Totten et al. in view of Jacobson et al. and Sang et al. as applied to claims 3, 5, 11, 17, 28, and 32-33 above, and further in view of Dener et al. (WO 98/04537) and Haider (1979).

Totten et al., Jacobson et al., and Sang et al. are applied as discussed above. The references lack corticosteroids.

Dener et al. teach compositions for treating hyperproliferative skin diseases and inflammatory skin conditions. Cromolyn and nedocromil are taught as equivalent cromoglycates. See abstract.

Haider teaches the treatment of atopic eczema with sodium cromoglycate. Compositions comprising sodium cromoglycate and hydrocortisone are disclosed to treat patients with severe inflammation. See pages 572-573.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the hydrocortisone of Haider to the composition of the combined references because a) Dener et al. teach cromolyn and nedocromil as equivalent cromoglycates for use in skin conditions, and Totten et al. teach nedocomil for the treatment of skin conditions; b) Haider teaches the combination of sodium cromoglycate (cromolyn) and hydrocortisone as treating significant inflammation in patient's with eczema (an inflammatory skin condition); thus, one of skill in the art would be motivated to add hydrocortisone to the composition of the combined references because of the expectation of synergistically decreasing the inflammation of skin conditions.

Claim 12 rejected under 35 U.S.C. 103(a) as being unpatentable over Totten et al. in view of Jacobson et al. and Sang et al. as applied to claims 3, 5, 11, 17, 28, and 32-33 above, and further in view of the Handbook of Cosmetic Science and Technology.

Totten et al., Jacobson et al., and Sang et al. are applied as discussed above. The references lack foams.

The Handbook of Cosmetic Science and Technology teaches emulsions and foams as interchangeable colloid systems. See page 67.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the emulsions of the combined references in the form of foams, as taught by the Handbook of Cosmetic Science and Technology, because of the expectation of achieving

Art Unit: 1617

equivalent colloidal systems and because of the expectation of achieving a product that can be more evenly and easily applied to a specific area of a user.

***Allowable Subject Matter***

The composition recited in instant independent claim 13 is neither anticipated nor rendered obvious over the prior art. The closest prior art is GB 2202145, which teaches a composition comprising 4% glyceryl monostearate, 10% liquid paraffin, 5% isopropyl myristate, 67.22% water, and 4% of a polar drug, and other ingredients. However this composition lacks disodium edetate, amphoteric surfactant, alkoxylated cetyl alcohol, triclosan, sorbitan tristearate or non-ionic emulsifying wax, and benzyl alcohol, and this composition additionally contains Cremophor A6, Cremophor A25, propyl hydroxybenzoate, methyl hydroxybenzoate, potassium sorbate, sodium acid citrate, and sodium hydroxide.

***Response to Arguments***

Applicant argues, "there is no suggestion in Totten et al. '145 that an increase in emulsion stability is needed or desired". This argument is not persuasive. The Examiner respectfully points out that page 3 of Totten et al. teach the addition of emulsifying agents in their compositions, wherein it is established in the art that emulsifying agents stabilize emulsions.

Applicant argues, "the cited references. . .fail to teach or suggest the unexpected results of the present invention". This argument is not persuasive, as the Examiner does not find the declaration filed 9/29/03, persuasive in showing unexpected results. Again, the Examiner respectfully directs Applicant to the guidelines for showing unexpected results. It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also

Art Unit: 1617

716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

The Examiner makes the following points, 1) the declaration does not appear to be commensurate in scope with the instant claims, as it is not even clear what the specific ingredients of the composition being tested were; 2) the declaration is additionally not commensurate in scope with the instant claims, as the instant independent claims are directed to any skin disorder and the declaration appears to be only treating eczema; 3) the instant declaration provided no comparative data; 4) the instant declaration provided no data of statistical and practical significant, as the "Notes" section of the data, merely comprises adjectives, and mostly describes the composition as "helping" patients, wherein "helping" is not a showing of an unexpected result/treatment.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after



Art Unit: 1617

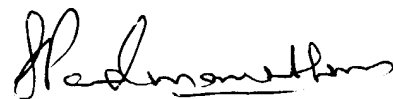
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is 571-272-0634. The examiner can normally be reached on M&R (5:30-4).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

lqw



**SREENI PADMANABHAN**  
**SUPERVISORY PATENT EXAMINER**